

## **REMARKS**

### **I. STATUS OF THE CLAIMS**

Claims 1-23 are pending in the present application. In the Office Action mailed August 19, 2004, claims 1, 2, 5-11, 1, 17, 22, and 23 were rejected. Claims 3, 4, 12-15, and 18-21 were objected to. Applicant appreciates the Examiner's indication that claims 3, 4, 12-15, and 18-21 would be allowable if rewritten in independent form.

By this Amendment, claims 1, 2, 5, 7, 8, 9, 10, 17, 18, 19, and 22 are amended. New claims 24-27 are added. No new matter is presented.

### **II. OATH/DECLARATION**

The oath or declaration was objected to as being defective because it was not signed by the inventor. The declaration was submitted in response to a Notice to Filing Missing Parts of a Nonprovisional Patent Application mailed on December 11, 2003. The Response to Notice to File Missing Parts was mailed on December 23, 2003.

A copy of the Response, including the signed declaration and the return postcard, is submitted herewith. It is believed that the declaration is sufficient and that no further action is required. However, if a deficiency remains, clarification is courteously solicited.

### **III. CLAIM REJECTIONS UNDER 35 U.S.C. §112**

Claims 1-15 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. In particular, claim 1 is rejected for reciting the limitation "further comprising" in line 5, which lacks antecedent basis. Claim 1 is amended hereby. As such, it is requested that this rejection be withdrawn. Additionally, claims 2, 5, 7-10, 18, and 19 are amended for consistency and to correct grammatical errors. No new matter is presented.

### **IV. CLAIM REJECTIONS UNDER 35 U.S.C. §102(b)**

Claims 1-2 and 5-11 are rejected under 35 U.S.C. §102(b) as being anticipated by FR2696340 to Muguerza ("*Muguerza*"). This rejection is respectfully traversed.

*Muguerza* is directed to an implant for altering the color of an iris. According to the Office Action, the implant of *Muguerza* “comprises a central circular opening (4) and at least one attaching means (5) disposed within the annular area” (Office Action, page 3). Applicant respectfully disagrees with this assessment.

*Muguerza* does not teach or suggest an implant for altering the iris color comprising a central circular opening, as claimed in claim 1 of the present application. Instead, the implant of *Muguerza* includes a central area (4) formed of a solid material that is transparent. Thus, there is no central circular opening, as provided in claim 1.

Furthermore, *Muguerza* does not teach or suggest an implant for altering the iris color comprising an attaching means disposed within the annular area, as recited in pending claim 1. Instead, the attaching means (5) of *Muguerza* is peripheral to the implant. Such a configuration is quite disadvantageous, as it causes the implant to extend beyond the iris and, therefore, can result in intraocular injuries in this region. In contrast to *Muguerza*, the implant of the present invention may avoid injuries in this area.

It is not clear how “the annular area can consist of the edges of the device as well as the any surface that is within that area”, as provided in the Office Action (page 3). Claim 1 provides that the implant is formed annularly thereby forming an annular area coming to rest on the iris of an eye. Thus, the annular area cannot be said to extend to regions well beyond the iris, as is depicted in Figure 2 of *Muguerza*.

The Office Action also states that the attaching means of *Muguerza* “consist of at least one opening in the annular area (11)”. Element (11) of *Muguerza* is a rigid protruding rib that stiffens the implant shown in the embodiment of Figure 3. The rib (11) is not an opening used to attach the implant to the eye.

Given that *Muguerza* fails to teach or suggest an implant having a central circular opening and an attaching means disposed within the annular area, *Muguerza* is not sufficient to support a rejection of claim 1 and its associated dependent claims 2 and 5-11 under 35 U.S.C. §102(b). As such, it is requested respectfully that this rejection be withdrawn.

## V. CLAIM REJECTIONS UNDER 35 U.S.C. §103(a)

Claims 16, 17, 22, and 23 are rejected under 35 U.S.C. §103(a) as being obvious over *Muguerza* in view of U.S. Patent No. 6,280,469 to Terry et al. ("*Terry*"). This rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference or combination of references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP §2142. Applicants submit that none of these criteria have been met.

There is no suggestion or motivation to modify the reference or to combine reference teachings, and there is no reasonable expectation of success in doing so. *Muguerza* is discussed above. *Terry* is directed to a thin, radially split, implantable artificial iris device. The device is threaded through a tiny slit near the periphery of the cornea (col. 2, lines 6-7). According to *Terry*:

[t]he device uniquely lends itself to very simple and manageable insertion-into-place by the fact that it permits smoothly slowing threading of itself into an eye...Such threading, according to the invention, takes place through an *extremely small surgical incision*...Insertion of the device is performed with little distortion of the natural tissues in the eye because of the fact that it can be threaded or snaked rotationally through such an incision...

(col. 1, line 66 through col. 2, line 10) (emphasis added).

The implant of *Muguerza* could not be implanted in this manner. Instead, a large incision would be required to accommodate the peripheral attachment means of the implant. Thus, to combine the teachings of *Muguerza* and *Terry* would defeat the stated advantages of the device of *Terry*.

Even if, *arguendo*, the references are properly combined, the combination fails to teach or suggest each and every element of Applicant's claimed invention. *Muguerza* does

not teach or suggest a method of locating and fixing an intraocular implant for altering the iris color, where the implant comprises an attaching means disposed within the annular area, as set forth in claims 16, 17, 22, and 23.

*Terry* does not cure this deficiency. *Terry* does not teach or suggest a method of locating and fixing an intraocular implant for altering the iris color, where the implant comprises an attaching means disposed within the annular area. In fact, the device of *Terry* is not attached in any manner. Mere placement of the device “securely seats the device in place” (col. 6, lines 25).

Given that there is no motivation to combine the references, and no motivation of success in doing so, and that the combination does not teach or suggest a method of locating and fixing an intraocular implant for altering the iris color, where the implant comprises an attaching means disposed within the annular area, it is submitted that the combination of *Muguerza* and *Terry* is insufficient to support a rejection of claims 16, 17, 22, and 23 under 35 U.S.C. §103(a). As such, it is requested respectfully that this rejection be withdrawn.

## **VI. NEW CLAIMS**

New claims 24-27 are presented. It is believed that new claims 24-27 are patentable over the art of record, as no reference teaches or suggests the subject matter presented therein.

### CONCLUSION

In view of the foregoing remarks, Applicants respectfully assert that the rejections of the claims as set forth in the Office Action mailed August 19, 2004 have been addressed and overcome. Applicants further respectfully assert that all claims (1-23) are in condition for allowance and request that a Notice of Allowance be issued. If issues may be resolved through Examiner's Amendment, or clarified in any manner, a call to the undersigned attorney at (404) 879-2437 is respectfully requested.

The Commissioner is hereby authorized to charge any fees due, or credit any overpayment, to Deposit Account No. **09-0528**.

Respectfully submitted,



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